

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Terry Keith Bryant
Serial No. : 10/767,396
Filed : 03/26/2004
For : METHOD OF IMPROVING MEDICAL
APPARATUS IN ORDER TO REDUCE OR
REPLACE ANCILLARY MEDICAL
ASSISTANCE BY EMPLOYING AUDIBLE
VERBAL HUMAN SOUNDING VOICES WHICH
PROVIDE THERAPEUTIC INSTRUCTIONS
AND ENCOURAGE USAGE AND GIVE
MEASUREMENTS AS NEEDED EMANATING
FROM THE APPARATUS'S BY USING
ELECTRONIC TECHNOLOGY
Examiner : Michael C. Astorino
Art Unit : 3736
Our File No. : 1023.8009

CERTIFICATION OF E-MAILING

I hereby certify that this correspondence, and any attachments thereto, is being filed via electronic mail with the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313.1450 on the date indicated below.

Betty Bernal
Name of Person Mailing Paper

Betty Bernal
Signature

11/09/2006
Date

AMENDMENT

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated August 10, 2006,
please amend the application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims,
which begins on page 5 of this paper.

Remarks/Arguments begin on page 17 of this paper.

Amendments to the Specification

1. Please replace the current Title to the following:

"SYSTEM TO REPLACE ANCILLARY MEDICAL ASSISTANCE BY EMPLOYMENT OF AUDIBLE, VERBAL, HUMANLIKE VOICES TO PROVIDE ENCOURAGEMENT, MEASUREMENTS, INSTRUCTIONS AND/OR THERAPY, AS NEEDED, IN RELATIONSHIP TO MEDICAL APPARATUSES FOR THE BLIND AS WELL AS THE SIGHTED"

2. Please amend the first paragraph of the Substitute Specification as follows:

"This Application+ claims the benefit of and priority to U.S. Application Serial No. #60/475,405 filed June 2, 2003. Portions of this application were also disclosed in and Disclosure Document # 504899 dated January 15, 2002 relate to
~~this specification herein and are incorporated by reference and the benefit of and priority to are claimed by the inventor.~~

3. Please amend the paragraph beginning at Page 11, line 8 as follows:

"Another, added advantage, to the present invention is the ability to retrieve data from the medical apparatus from a base station through radio frequencies, or whatever technology allows such performance, ~~such as a palm pilot or CP, that~~ to provide information without the doctor having to be present at the location of the patient or user. This function provided by the present invention confirms a well known principle valued by the medical profession that, "the more one uses the prescribed treatment, the faster one recuperates." With the conception of the present invention a new step in medical progress will be made, as the patient will be using the device on their own,

through the use of the present invention thus replacing the need for ancillary medical personnel, decreasing cost. Thus, this cost effective new device as well as a health benefit for the patient, disposable accordingly due to the extremely low cost for producing the new invention, or permanent according to the manufacturers desire will not only help the patient fulfill their goals for his or her medical progress as needed, but also save the hospital, a considerable amount of money, as the present invention will eliminate the need for supervised attention by ancillary medical assistance, replacing those present positions and responsibilities, by giving incentive to the patient, or gauging the patient's performance through the function of the present invention as specified herein, capable of performing mathematical and logical calculations" and decision logics which together constitute the "functional program", which is normally a mandatory task perform by an ancillary medical assistant, all which will be accomplished by the employment of audible, verbal, simulated humanlike voices applied to, housed within, attached to, or separate in synthesis with those medical apparatus requiring such, for encouragement and guidance from the medical apparatus itself to prompt and increase patient's usage through the employment of human sounding words emulating in synthesis with the medical apparatus or it's general area of location, for the purpose of eliminating ancillary medical assistance.

4. Please amend the paragraph beginning at Page 17, line 23 as follows:

"Fig. 4 shows the details of the Alternative Embodiment of Audible Response Unit 1 of Fig. 3 in relation to Medical Apparatus 10 and Speaker 3. In Fig. 4, the Power Supply 4 connects to Microcontroller Unit 7, Audio Storage Unit 6, and Audio Amplifier Unit 8 through a set of electrical connections

labeled 403, 502 and 500, respectively. The Power Supply 4 also connects to the Gauge 2 within the Medical Apparatus 10 through a set of electrical connections labeled 402. In all other respects, the Alternative Embodiment of Audible Response Unit 1 of Fig. 4 is the same as the Preferred Embodiment of Audible Response Unit 1 in Fig. 2. In all other respects, description of the operation of the Alternative Embodiment of Present Invention in Fig. 3 is the same as the description of operation of the Preferred Embodiment of Present Invention in Fig. 1.”.

Amendment to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claims 1 and 2 (cancelled).

Claim 3 (currently amended) ~~An improved~~ A system for replacing human ancillary medical assistance needed to prompt, encourage and guide a blind as well as a sighted user in relationship to utilization of medical apparatuses, said system comprising:

a medical apparatus used for a particular medical or therapeutic function, as needed, of a type that conventionally requires ~~requiring~~ live human ancillary medical assistance to ensure, prompt, inspire, entice, command, respond, inform or encourage recommended or required therapeutic use by a patient using said medical apparatus to prompt, encourage, give measurements or guide a user in connection with utilization of said medical apparatus or in correlation with any medical procedure working in synthesis with said medical apparatus;

a self-contained electronic assembly for replacing live human ancillary medical assistance by automatically verbally prompting or guiding a blind or sighted user to initiate use of the medical apparatus, as needed, and by automatically providing verbal encouragement and guidance to the user when utilizing said medical apparatus, when required, without live human ancillary medical assistance being given for such purposes, said self-contained electronic assembly comprising a single microcontroller unit controlled by a functional program and an audio storage unit, said audio storage unit having at least one stored audible verbal message for prompting and initiating use or providing understanding for the user when utilizing the medical apparatus, as needed, and at least one stored audible verbal message for

guiding the user's use of, ~~enticing, commanding, inspiring, responding, informing or the patient to use~~ said medical apparatus ~~or which provides therapeutic guidance to the patient regarding use of the medical apparatus;~~ wherein the functional program ~~controls~~ instructs the single microcontroller unit when required regarding the operation of said electronic assembly, including the function of prompting, encouraging and guiding messages for the user, thus, replacing and eliminates the need for ancillary medical assistance when the user is utilizing therapeutically guiding the patient to use said medical apparatus;

means for powering said electronic assembly; and

a speaker in communication with said electronic assembly for receiving one of the ~~said at least one~~ stored audible verbal message from said audio storage unit upon direction from said microcontroller unit and transmitting the at least one stored audible verbal message directly to the patient user to encourage compliance with the ~~therapeutic~~ guidelines for utilization of said medical apparatus as needed by the patient user without the necessity of having a live human ancillary medical assistant instruct or encourage present with the patient user for such purposes.

Claim 4 (currently amended) The ~~improved medical apparatus~~ system of claim 3 wherein said self-contained electronic assembly further including means for verbally indicating to the patient user a measurement or result achieved by the patient user from the performance of the required or recommended therapeutic procedure with said medical apparatus; wherein the measurement or result achieved is calculated through mathematical and logic calculations performed by said single microcontroller unit based on instructions received from the functional program.

Claim 5 (currently amended) The system ~~improved medical~~

~~apparatus~~ of claim 4 wherein said means for verbally indicating having means for converting digital audio data into continuous analog signal ~~through regeneration~~.

Claim 6 (currently amended) The system ~~improved medical apparatus~~ of claim 4 wherein said means for verbally indicating comprising:

means for receiving analog signals relating to the user's performance with the medical apparatus;

a level setting unit providing a performance level or goal for said medical apparatus; and

means for converting the receiving analog signals from said medical apparatus into digital data;

wherein an encouragement message sent from audio storage unit to the speaker by direction of the single microcontroller is based on the analog signal received from said medical apparatus and the performance level or goal provided by the level setting unit.

Claim 7 (currently amended) The system ~~improved medical apparatus~~ of claim 6 wherein said means for receiving is a gauge provided on said medical apparatus and a gauge connector in communication with the gauge and a signal input unit of said single microcontroller unit.

Claim 8 (currently amended) The system ~~improved medical apparatus~~ of claim 7 wherein said level setting unit in communication with said signal input unit.

Claim 9 (currently amended) (currently amended) The system ~~improved medical apparatus~~ of claim 3 wherein said single microcontroller unit directs the audio storage unit to send a first verbal message to the speaker in order to prompt the user to initiate use of said medical apparatus device ~~by the user as needed in relationship to said medical apparatus~~.

Claim 10 (currently amended) The system ~~improved medical~~

~~apparatus~~ of claim 9 wherein ~~in relationship to said medical apparatus being used for powering said electronic assembly,~~ said self-contained electronic assembly having a timing device for determining when to automatically send said at least one stored verbal message from said audio storage unit to said speaker in order to prompt, ~~remind, entice, inspire or encourage~~ the patient user to initiate use of said medical apparatus as needed in relationship to said medical function of said medical apparatus as needed ~~to perform the required procedure as therapeutically required or recommended for said medical apparatus.~~

Claim 11 (currently amended) The ~~system improved medical apparatus~~ of claim 10 wherein said single microcontroller unit is programmed to direct the audio storage unit of output signals at a set time to send a first verbal message to the speaker in order to prompt the user to initiate use of said medical apparatus ~~device by the user~~ from the audio response relayed from a Signal Output Unit of the electronic assembly at a rate appropriate for the regeneration of an audible response from the audio data.

Claim 12 (currently amended) The ~~system improved medical apparatus~~ of claim 9 wherein said single microcontroller unit continues to direct the audio storage unit to send the first verbal message or another verbal message to the speaker on a spaced apart continuous basis until said single microcontroller unit learns that the user has ~~begun to perform~~ initiated performance of the required procedure with said medical apparatus.

Claim 13 (currently amended) The ~~system improved medical apparatus~~ of claim 9 wherein after the required procedure has been performed by the user said single microcontroller unit is programmed to wait for a predetermined therapeutic time period before automatically directing said audio storage unit to send a next initial verbal prompting message to the user for prompting

the user to ~~perform~~ initiate another required procedure; wherein as needed the user is prompted and encouraged to perform multiple required procedures with said medical apparatus device being employed during a single day period as therapeutically required or recommended for said medical apparatus.

Claim 14 (currently amended) The system improved medical apparatus of claim 3 wherein said self-contained electronic assembly further comprising means for verbally indicating comprising:

means for determining a measurement or result achieved by the user from performing the required procedure with said medical apparatus as needed; and

one or more verbal encouragement messages stored within said audio storage unit;

~~an audio response unit;~~

~~means for powering said audio response unit; and~~

~~a speaker in communication with said audio response unit;~~
~~and~~

wherein a signal corresponding to the measurement or result achieved by the user is sent by said means for determining to the audio ~~response~~ storage unit which provides ~~generates~~ an appropriate verbal encouraging or guiding message which is sent to the speaker to verbally indicate to the user the measurement or result determined and the encouraging or guiding message also ~~sends a verbal functional message appropriate for the measurement or result determined according to a performance level or goal for the medical apparatus.~~

Claim 15 (currently amended) The system improved medical apparatus of claim 14 wherein said self-contained electronic assembly further comprising a timer, ~~controlled by a functional program of said microcontroller unit,~~ for dictating when audio messages are sent to the speaker by said audio response unit

~~based on instructions contained within the functional program* wherein the functional program controls a timing unit to allow the appropriate time for the therapeutic use of said medical apparatus according to said medical apparatus.~~

Claim 16 (currently amended) The ~~system improved medical apparatus~~ of claim 15 wherein the verbal ~~encouragement encouraging or guiding~~ message sent is chosen from a plurality of verbal messages stored in said audio data message storage unit; wherein, in relationship to the functional program stored within the microcontroller unit that defines the behavior of said medical apparatus in accordance to a defined function, at least one of the plurality of verbal ~~encouragement encouraging or guiding~~ messages is used where the measurement or result determined is lower than the target measurement and at least one of the plurality of verbal encouragement messages is used where the measurement or result determined is higher than the target measurement; wherein the plurality of verbal messages allow an appropriate verbal message to be selected, according to the user's measurement or result performance of the required procedure according to said medical apparatus.

Claim 17 (currently amended) ~~An improved A system for replacing human ancillary medical assistance needed to prompt, encourage and guide a blind or sighted user with the use of a medical apparatus, said system comprising:~~

a medical apparatus having a particular medical or therapeutic function and of a type that conventionally requires live human ancillary medical assistance ~~to ensure or encourage recommended use of said medical apparatus by a patient to prompt, encourage and guide a blind or sighted user in connection with the use of said medical apparatus or in correlation with any medical procedure working in synthesis with said medical apparatus; and~~

a self-contained means for replacing live human ancillary medical assistance by automatically verbally prompting the patient user without live human ancillary medical assistance being given to initiate use of said medical apparatus to perform a medical procedure achieved through the use of said medical apparatus without having to have a live human ancillary medical assistant physically instructing or encouraging present with the user patient;

wherein said means for replacing live human ancillary medical assistance by automatically verbally prompting disposed within or attached to a housing of said medical apparatus or disposed within its own housing separate from said medical apparatus.

Claim 18 (currently amended) The system improved medical apparatus of claim 17 wherein said means for verbally prompting is either disposed within or attached to said housing of said medical apparatus, and said improved medical apparatus further comprising means for verbally indicating and verbally responding accordingly to a patient user based on a measurement or result achieved by the patient user from the user's patient's performance of the required procedure and without the necessity of a live human ancillary medical assistant, said means for verbally indicating and verbally responding disposed or attached to a same within the housing as said means for verbally prompting.

Claim 19 (currently amended) The system improved medical apparatus of claim 18 wherein said means for verbally indicating comprising:

means for determining a measurement or result achieved by the patient user from performing the required procedure with said medical apparatus;

an audio response unit;

means for converting digital data into analog through regeneration;

a signal output unit in communication with said means for converting;

wherein audio data is successively relayed to the Signal Output unit at a rate appropriate for the regeneration of the audible response according to said medical apparatus;

means for powering said audio response unit; and

a speaker in communication with said signal output unit;

wherein an output signal corresponding to the measurement or result achieved by the patient user is sent by said means for determining to the audio response unit which provides ~~generates~~ a verbal message relayed from stored audio data which is sent to the speaker to verbally indicate to the patient user said measurement or result achieved and also sends a verbal functional encouragement message appropriate for the measurement or result determined according to the ~~therapeutic~~ function of said medical apparatus as needed.

Claim 20 (currently amended) The system ~~improved medical apparatus~~ of claim 19 wherein said audio response unit including an audio message storage unit which sends a the verbal encouragement message to the speaker based on a comparison of the measurement or result achieved to a target measurement or result in relationship to said medical apparatus as needed.

Claim 21 (currently amended) The system ~~improved medical apparatus~~ of claim 19 wherein the verbal encouragement message sent is chosen from a plurality of verbal messages stored in the audio message storage unit; wherein at least one of the plurality of verbal encouragement messages is used where the measurement or result determined is lower than the target measurement or result and at least one of the plurality of verbal encouragement messages is used where the measurement or result determined is

higher than the target measurement or result; wherein the plurality of verbal messages allow an appropriate verbal message to be selected according to the ~~patient's~~ user's measurement or result performance of the required procedure according to said medical apparatus as needed.

Claim 22 (currently amended) An automated verbal prompting and indication device for a medical apparatus to be used by a blind as well as a sighted user, said medical apparatus of a type that conventionally requires live human ancillary medical assistance to ensure use is initiated by the blind as well as the sighted user in order ~~or~~ to prompt encourage give measurements or guide use of said medical apparatus as needed, said automated prompting device comprising:

means for replacing live human ancillary medical assistance by automatically verbally prompting a ~~patient~~ user without live human ancillary medical assistance to initiate use as needed for said medical apparatus to ~~perform a required~~ perform or guide a ~~or~~ recommended procedure achieved through utilization ~~the use of~~ said medical apparatus, without having to have a live human ancillary medical assistant physically instruct, encourage or provide information to ~~present with the user patient~~; wherein said verbal prompting is achieved without instructions, encouragement or information about the medical apparatus from a live human ancillary medical assistant or from a remote location ~~the physical presence of an ancillary medical assistant with the patient~~; and

means for verbally indicating a response as needed and verbally responding accordingly to utilization of said medical apparatus a patient when based on a measurement or result being achieved by the user patient from the user's performance of the procedure according to said medical apparatus and without the ~~physical presence of an~~ encouragement or instructions from a live

human ancillary medical assistant or from a remote location with the patient.

Claim 23 (currently amended) The automated verbal prompting and indication device of claim 22 wherein said means for verbally prompting ~~comprises an~~ is part of a self-contained electronic assembly in communication with a speaker and means for powering said electronic assembly, said electronic assembly comprising a single microcontroller unit and an audio storage unit, said audio storage unit having at least one stored verbal message for prompting the user patient to initiate use of said medical apparatus as needed to perform the required procedure; wherein said single microcontroller unit automatically directs the audio storage unit to send a first verbal message to the speaker in order to prompt the user to initiate use of said medical apparatus ~~device~~ by the user patient.

Claim 24 (currently amended) The automated verbal prompting and indication device of claim 23 wherein after the required procedure has been performed by the user patient said microcontroller unit is programmed to wait for a predetermined ~~therapeutic~~ time period, as needed, before directing said audio storage unit to send a next verbal prompting message to the user patient for prompting the user patient to perform initiate another required procedure; wherein the user patient is automatically encouraged by said electronic assembly communicating through the speaker to perform multiple required procedures with said medical apparatus ~~device~~ during a single day period as ~~therapeutically~~ required or recommended without having a live human ancillary medical assistant present or without having to receive a communication from a remote location.

Claim 25 (currently amended) The automated verbal prompting and indication device of claim 22 wherein said means for verbally indicating comprising:

means for determining a measurement or result achieved by the user from performing the required procedure with said medical apparatus;

an audio response unit;

means for powering said audio response unit; and

a speaker in communication with said audio response unit;

wherein a signal corresponding to the measurement or result achieved by the user is sent by said means for determining to the audio response unit which generates a verbal message which is sent to the speaker to verbally indicate to the user said measurement or result achieved and also sends a verbal functional message appropriate for the measurement or result determined in accordance with particular guidelines for said medical apparatus.

Claim 26 (currently amended) The automated verbal prompting and indication device of claim 25 wherein said audio response unit including an audio message storage unit which sends a verbal encouragement message to the speaker based on a comparison of the measurement or result achieved to a ~~target~~ measurement or result in accordance with said medical apparatus as needed.

Claim 27 (currently amended) The automated verbal prompting and indication device of claim 26 wherein the verbal encouragement message sent is chosen from a plurality of verbal messages stored in the audio message storage unit; wherein at least one of the plurality of verbal encouragement messages is used where the measurement or result determined is lower than the target measurement or result and at least one of the plurality of verbal encouragement messages is used where the measurement or result determined is higher than the target measurement or result; wherein the plurality of verbal messages allow an appropriate verbal message to be selected according to the user's measurement or result performance of the required procedure as needed according to said medical apparatus.

Claim 28 (previously presented) The automated verbal prompting and indication device of claim 22 further comprising means for storing information relating to the user ~~patient's~~ usage of said medical apparatus or to measurements or results achieved by the user ~~patient~~ from use of said medical apparatus as needed.

Claim 29 (cancelled).

Claim 30 (previously presented) The automated verbal prompting and indication device of claim 28 for comprising means for transmitting the stored information to a retrieving location that is remote to whatever current location of said medical apparatus.

Claim 31 (cancelled).

Claim 32 (new) The system of claim 3 wherein said medical apparatus contained within a first housing and said self-contained electronic assembly contained within a separate second housing.

Claim 33 (new) The system of claim 3 wherein said medical apparatus and said self-contained electronic assembly contained within a single housing.

Claim 34 (new) The system of claim 17 wherein said medical apparatus contained within a second housing which is separate from the housing for said means for automatically verbally prompting.

Claim 35 (new) The system of claim 17 wherein said housing containing said means for automatically verbally prompting also containing said medical apparatus.

Claim 36 (new) The automated verbal prompting and indication device of claim 22 further comprising a housing containing both said means for automatically verbally prompting and said means for verbally indicating and verbally responding.

REMARKS

This Amendment is responsive to the Office Action having a mailing date of August 10, 2006.

Claims 3-25 and 27 have been amended. Claims 32-36 have been added. No new matter has been inserted. Claims 3-28 and 30 and 32-36 remain pending in the application. Applicant respectfully requests reconsideration of the Examiner's rejections.

The Title has been shortened. The specification has been amended to address the Examiner's objections to the priority claims and alleged new matter. The specification has also been amended to include reference numerals 502 and 500 originally shown in Figure 4 but not mentioned in the specification. Figure 5 has been amended to delete reference numeral 15. A replacement sheet for Figure 5 is enclosed herewith.

The Edwards claim rejections.

Applicant incorporates by reference its previous arguments regarding Edwards. Applicant appreciates the Examiner's recognition that Edwards does provide a spirometer which provides audible and verbal instructions. However, Applicant respectfully notes that the audible/verbal instructions provided by Edwards are for the limited purpose of using the Edwards spirometer. It is readily apparent that Edwards fails to teach the claimed device of Applicant.

Edwards is a highly mechanically complicated medical device which requires physical adjustments be made to the device for proper use. The Edwards device is a multi-function modular device encompassing more than one breathing procedure which requires unthreading/threading and unscrewing/screwing in different components of the device, such as, but not limited to, the mouthpiece using a mouthpiece-to-neck attachment means. Col 4,

lines 51-54. Furthermore, Edwards also requires configuring the rotor blade in relationship to sensitivity to one of two options depending on whether the user is performing an exhaling or inhaling procedure with the device. Col. 9, lines 13-39. Additionally, Edwards also indicates that the spirometer needs to be frequently calibrated and recalibrated by the patient or user to finely adjust how easily the rotor rotates in response to given air flow. Col. 10, lines 39-42. The fine and complicated details of how the Edwards spirometer is calibrated are then discussed in the same paragraph. For example, it is indicated that calibration can be performed with a bearing screw (phillipshead or otherwise) that is moved slightly up or down as desired to tighten or loosen the spindle and adjust the sensitivity of the rotor with respect to any given airflow. Col. 10, lines 42-47. Sensitivity is defined as "of such a nature to be easily effective". Thus, in another words, the Edwards sensitivity easily affects his apparatus if not performed correctly by the patient.

Edwards also requires the user to access the calibration screw through an opening beneath the spirometer where a screwdriver can pass. Col. 10, lines 47-49.

Furthermore, Edwards also uses a filter sack which changes color to visually indicate to the user that the mouthpiece and sack combination have already used and thus, to remove the used mouthpiece and replace it with a new one. Col. 5, lines 2-12.

Additionally, Edwards also discusses the modularity of the his device, including the attachment and detachment of several modular sections such as, the rotor section, upper filtration section, lower filtration section, detection and electronics section and air outlet section to and from one another. Col. 8, lines 20-25.

These necessary procedures to ensure that the Edwards device is working properly and are not trivial actions and require that the user of the Edwards device be at least able to see, and apparently is also knowledgeable in the exact assembly and adjustment procedures in order for the patient to use the Edwards device. Being that this is unlikely, Edwards device would then require that live ancillary medical assistance be present for performing these procedures and is a particularly significant problem if the user is blind should assistance be unavailable.

Edwards does disclose providing an alleged voice system containing prerecorded instructions to walk the user through the use of the Edwards spirometer, which should apparently also include the ability to walk the user through the process of calibration of the device itself. Thus, thereby obviating the need for a technician (ancillary medical assistance) to provide such instructions and allowing the Edwards spirometer to be employed as a personal use device. Col 11, lines 13-17. Thus, Edwards teaches that no technician is intended to be present, making it clear that the Edward's device is limited to sighted users who must respond to the complex calibration techniques that the Edwards device instructs, as well as having accessibility to the proper calibration tools, in view of the above description procedures, attachments, sensitivity of rotor blades, detachments and calibrations that must be performed by the user on the Edwards device. Therefore, given these way beyond simple required procedures that must be performed by the sighted user, Applicant respectfully questions, whether a typical sighted user is qualified or can be trusted to correctly perform these procedures that a qualified medical technician should perform on the Edwards device.

Furthermore, the standards of the American Medical Association ("AMA") relating to patient use of personal use

devices indicate that calibration must be of a type that is convenient, easily obtainable and usable. As stated above, Edward's device is one that a blind person in particular could not use, due to the complexity of the calibration. Additionally, in a hospital environment, where a sighted patient is seriously ill, it is doubtful that a patient could be asked to perform these required procedures on the Edwards device. Thus, it is also doubtful that the Edwards device satisfies the AMA requirements, even when used by a sighted user, since the calibration requirements are so complex, in consideration of the AMA standards of being convenient and easily usable. Furthermore, it is doubtful that a user comes to the hospital having a screwdriver for calibration purposes, yet alone the correct size screwdriver. Thus, the complexity of calibration for the Edward's device is more complex than a normal personal use device and requires a greater calibration process than those calibration requirements required by the AMA. It is difficult to imagine how one could expect a blind, or even a sighted patient, to use the personal use device Edwards teaches due to the detailed adjustments Edwards requires.

Applicant claims, as amended, indicate that the user of Applicant's medical device can be sighted or blind. Thus, given the physical demands for properly using the Edwards device, it is readily seen that such device could not be used, in particularly by a blind user due to the complexity of calibration, unless a live ancillary medical assistance were present to perform the adjustments required by Edwards.

Edwards is a complex multiple, all inclusive breathing apparatus with complex requirements for usage that are far beyond the normal capability of the sighted or the blind patient, due to these complex procedures for use and would not be possible to be used without a live ancillary medical assistant. As a multiple

purpose breathing apparatus requiring different breathing test to be performed at different times, it would be evident that medical assistance would be needed to inform the blind, as well as the sighted user, of which of the various tests to be performed, as well as which time to perform such needed breathing medical test. Thus, the specific structural nature of the Edwards device prevents it from being considered the type of "a medical apparatus" as claimed by Applicant.

As now claimed Applicant's invention permits a sighted or blind user to use the medical apparatus without the presence of ancillary medical assistance to perform any normal ancillary task. Given that Applicant's claims specifically indicate that the medical device can be used by both blind and sighted users, Applicant's comments removing Edwards as a proper medical apparatus should not be considered unduly narrow and are in fact in concert with the broadest interpretation of the claims. Furthermore, claims 3 and 17 do in fact now claim that live human ancillary medical assistance is not given to the sighted or blind user for purposes of prompting initial use of the medical apparatus or informing, instructing or guiding the sighted or blind user, in connection with their use of the medical apparatuses. Claim 3 also now claims that the medical device conventionally required live human medical ancillary assistance, which should be interpreted to mean in the past such medical apparatus would have needed live human assistance. The claims now also state that this previously live human assistance is replaced through the components of the claimed invention.

Edwards also does not prompt a user to initiate use or begin using the spirometer. By this Amendment, the claims have been amended to change the language "prompt use of said medical apparatus" to "prompt the user to initiate use of said medical apparatus". This revision in the claim language now more clearly

shows that Applicant's claimed invention on its own, automatically begins prompting the user to use the medical apparatus as needed. Edwards only provides certain verbal instructions on how to use the medical apparatus after the user or other individual, on his or her own, has activated, calibrated or recalibrated the medical apparatus. Edwards does not prompt the user to calibrate or recalibrate the medical apparatus or to activate or initiate use of the medical apparatus. It is well known to one skilled in the medical field that compliance with utilization by the patient is the most important process for beginning patient recovery.

Accordingly, Applicant respectfully submits that Edwards fails to disclose Applicant's claimed invention. As such, Applicant respectfully requests that the rejection of claims 1-5, 9-11, 14-15 and 17 in view of Edwards be withdrawn.

The Wessel claim rejections.

Wessel only teaches providing rewards through a visual display, without any predetermined voice guidance taught being part of the Wessel device itself. The use of visual displays is continuously discussed throughout Wessel. For example, the Wessel controller includes a first display 30 to display video-game graphics, charts, tables or other information. Col. 2, lines 61-62 and Col. 4, lines 52-54. A second display, separate from the first display, for displaying medical information is provided on a medical diagnostic cartridge. Col. 2, lines 64-66 and Col. 5, lines 7-8. Display 30 is also required to display to the user the reward codes, games, prizes and other non-medical incentives. Col. 5, lines 34-36. Data retrieved is shown on display 60 of cartridge 50. Col. 13, lines 40-42. The above are only a handful of examples of the use of visual displays in the Wessel patent. Given this reliance on visual displays by Wessel, it is clear

that the Wessel device cannot be used by the blind or the sighted user without having live ancillary medical assistance, especially given the requirements for knowledge or familiarity of the complexity of aforementioned display equipment, thus requiring guidance for operation. Also, the sighted user may not be familiar with the operation of a GAMEBOY or how to get text messages from a cell phone or the other various embodiments discussed in Wessel, which would thus require live ancillary medical assistance to teach the user in such operations.

Furthermore, Wessel's glucose reader cartridge is inserted into a handheld video-game controller and the visual rewards provided can be associated with playing the video-game. Col. 4, lines 50-51; Col. 9, lines 63-67. The playing of the video-game and reviewing the visually displayed rewards, shows that Wessel is limited for use by a sighted user and could not be used by a blind person. Wessel's device does not provide self-contained verbal instructions, as claimed by Applicant, for prompting the use to initiate use of the device and for guiding the user during the use of the device. As mentioned above, with respect to Edwards, it is well known to one skilled in the medical field that compliance with use initiation by a patient is the most important process for beginning patient recovery.

The Examiner also relies on the description in Wessel indicating that a "nice job" or other encouragement message is displayed on display 30 of telephone 205. Col 16, lines 28-31. The Examiner also notes that Wessel states that at a different step the message can include videos, graphics, text, and/or audio to name several examples. Col 16, lines 25-27.

This description in Wessel should not be confusingly interpreted to mean that Wessel is capable of giving audible verbal instructions or prompts, as claimed by Applicant. Wessel is actually silent regarding the device providing audible verbal

instructions or prompts. When referring to "audio", Wessel is discussing sound imitations, absent of wordage. Text messages in Wessel are only described and discussed as being visually displayed. Audio is defined as the reproduction of sound and does not means audible verbal instructions to prompt and guide usage, such as a human voice contained within the apparatus as claimed by Applicant. Throughout the Wessel disclosure it is consistently described that the visual display is the predominant form of reward and "audio" is only used for an alarm system to alert the patient.

Furthermore, with the cellular telephone and other embodiments referred to by Wessel, the patient or other user is required to have the ability to adjust or maintain current medical test results or other parameters. Col. 12, lines 37-38. Clearly, under normal conditions, a blind or sighted patient in a hospital is not qualified to adjust his or her own medical test results and such adjusting would be too complex and thus would require ancillary medical assistance.

At column 9 line 33, Wessel teaches that the person utilizing his device is a patient. A patient is defined as "a person under medical care". At column 9. line 64 of Wessel, it is stated that a "GAME BOY controller is used only to display reward codes, games, prizes, and other information or incentives that are not directly medically related." Thus, all patients (individuals under medical care) using the Wessel device are expected to comprehend the way to use a GAME BOY, cellular telephone, as well as being expected to know how to send or retrieve messages with these types of devices. It is readily apparent that all patients will not be familiar with GAME BOYS, cellular telephones, and sending or retrieving messages from these devices. Thus, ancillary assistance must be provided to teach the patient (who is obviously sighted in view of the above

comments) in the use of these devices. A further problem with Wessel that is avoided and irrelevant with Applicant's claimed invention, is that the operation of a GAME BOY or cellular telephone is not a known teaching per the standards of the AMA requirements for ancillary medical assistants during his or her training. Thus, the ancillary medical assistant may not be able to properly train the patient in the operation of these non-medical devices that Wessel requires.

Accordingly, Wessel cannot be used by (1) every patient without proper ancillary assistance, especially patients who have never used a GAME BOY or cellular telephone, (2) in every hospital setting, especially since electronic devices and cellular telephones may not even be permitted to be operated in the hospital. Again, given the dependence on visual displays Wessel is also limited to sighted users who are previously knowledgeable with the operation of a GAME BOY or cellular telephone or any other non-medical devices required to perform the function of Wessel's invention.

Applicant's claimed system includes conventional medical apparatuses making the claimed invention totally different then the Wessel device. Applicant's claimed system is not dependent on any outside non-medical devices to be used, as taught by Wessel. These outside components required by Wessel, must be used to provide the function of his device, or invention, such that the Wessel video game system and medical cartridge should not be considered a complete medical device by themselves.

Since during use of the Wessel's device visual text messages can come from a remote location, Wessel also discusses encrypting medical testing parameters, which require visual text messaging. Col. 12, lines 47-50. This again is completely different than Applicant's claimed audible verbal messages.

Wessel also fails to verbally indicate the glucose reading to the user. Wessel only discloses two different visual displays 30 and 60. In certain embodiments, certain messages from a remote location can be transmitted to the Wessel device. Thus, Wessel does not have an audio storage or audio response unit where messages are stored. Wessel provides no audible, verbal instructions, guidance or teachings to a blind or sighted user for using the Wessel device in any of its embodiments (i.e. cellular, GAME BOY, Palm Pilot, etc.). Even the sighted user, especially in a hospital setting, would have difficulty using the Wessel device without ancillary medical assistance.

None of the preferred embodiments of Wessel, contain an audio response unit where audible verbal messages are stored. Nowhere in Wessel, does it provide or store audible, verbal instructions for the sighted or blind in the complexity of using the Wessel device.

Additionally, as the Wessel messages can be sent from a remote location, the Wessel device itself does not decide which message to select from a plurality of stored messages, which to the contrary, Applicant's system being synthesis with medical apparatuses does decide.

Wessel does not teach nor provide any verbal instructions for retrieving any messages required for display per the function of his device. Nor does Wessel in any way make allowances for the blind or even the sighted, in order to show the procedures needed to perform the retrieval as taught for the function of Wessel's devices and retrieval is required as a fundamental portion of the Wessel patent. Wessel does not make allowances for the blind, incapacitated, or the seriously ill, (even diabetics have often have problems seeing), or other diseases. In addition to needing instructions for operating a medical device, the user most likely will also need instructions for using the non-medical equipment

necessary to perform retrieval of display techniques taught by Wessel. Thus, the required ancillary medical assistant would also have to be familiar and/or trained in the usage of Wessel's claimed retrieval devices; Palm Pilot, Game Boy, and a variety of other devices including voice or other telephone message retrieval...such as text or MSM messages. Applicant's claimed invention significantly differs from Wessel as it provides a novel method and system incorporating a self-contained electronic assembly component that requires no patient or ancillary medical assistant to program any features or retrieve any messages. Applicant's claimed invention avoids the complexity of utilizing any device, medical or otherwise, as taught by Wessel, which becomes multiplied immensely, when one is ill, or blind.

With respect to certain claims, Wessel does not disclose a gauge and does not require the user relating to performance a therapeutic or medical procedure using the device. Rather it merely reads a glucose level from a strip inserted into the device/cartridge. Accordingly, the claims discussing a gauge are also not shown by Wessel.

The Wessel patent also does not on its own automatically begin prompting the user to initiate use of the medical apparatus. Applicant's claimed electronic assembly uses a single microcontroller unit to perform all functions. To the contrary, Wessel requires a first processor 95 for processing information regarding the glucose readings and a second processor 130 for controlling the reward to provide the user, which is also a visual reward that the blind would be unable to use.

Furthermore, Wessel does not replace ancillary medical assistance, as it describes a live human (doctor, nurse) receiving the glucose score and then based on such score remotely sending a verbal message. Col. 4, lines 8-34; Col. 14, lines 15-22. Applicant's electronic assembly, which includes the audio

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response unit, is claimed as being self-contained, which is readily seen in the drawings and the associated description of the drawings. Applicant's verbal messages are stored and produced from the electronic assembly without any further remote signal or transmissions. Wessel fails to disclose this claimed feature.

Accordingly, Applicant respectfully submits that the Wessel invention fails to disclose Applicant's claimed invention. As such, Applicant respectfully requests that the rejection of claims 3-28 and 30 in view of Wessel be withdrawn.

In view of the above, Applicant respectfully requests that the Examiner withdraw all Section 102 rejections. Favorable action is respectfully requested. Applicant has completely responded to the Office Action dated August 10, 2006.

If there are any additional charges, including extension of time, please bill our Deposit Account No. 503180.

Respectfully submitted,



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